



U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

**INFORMATION DISCLOSURE STATEMENT**

Docket Number:  
2664/57104

Application Number  
10/606,403

Filing Date  
June 25, 2003

Examiner  
To be assigned

Art Unit  
1625

Invention Title  
**NOVEL PROCESS FOR PREPARING AND ISOLATING  
RAC-BICALUTAMIDE AND ITS INTERMEDIATES**

Inventor(s)  
**Ben-Zion DOLITZKY et al.**

Address to  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

Date: 10/6/03 Reg. No. 46,877

Signature: *[Signature]*  
Siu K. Lo

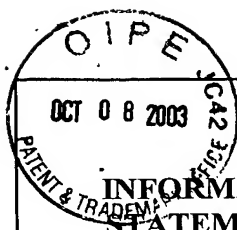
Sir:

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 35 U.S.C. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
2. Copies of each patent, publication or other information listed on the modified PTO form 1449 are not enclosed since they were previously cited by or submitted to the Patent Office in prior application Serial No. 10/170,721 which is relied upon for an earlier filing date under 35 U.S.C. 120.
3. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due, the Commissioner is authorized to charge Deposit Account No. 11-0600 for such fees. A duplicate copy of this communication is enclosed for charging purposes.

Dated: 10/6/03

By: *[Signature]*  
Siu K. Lo (Reg. No. 46,877)

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> | <b>DOCKET NO.</b><br>2664/57104     | <b>SERIAL NO</b><br>10/606,403 |
|  | <b>APPLICANT</b><br>Dolitzky et al. |                                |
|  | <b>FILING DATE</b><br>June 25, 2003 | <b>GROUP</b><br>1625           |

**U. S. PATENT DOCUMENTS**

| EXAMINER<br>INITIAL | PATENT<br>NUMBER | PATENT<br>DATE     | NAME           | CLASS | SUBCLASS | FILING<br>DATE* |
|---------------------|------------------|--------------------|----------------|-------|----------|-----------------|
|                     | 4,636,505        | January 13, 1987   | Tucker         |       |          |                 |
|                     | 6,358,985        | March 19, 2002     | Anthony et al. |       |          |                 |
|                     | 6,306,874        | October 23, 2001   | Fraley et al.  |       |          |                 |
|                     | 6,291,504        | September 18, 2001 | Nugiel et al.  |       |          |                 |
|                     | 6,184,249        | February 6, 2001   | Sovak et al.   |       |          |                 |
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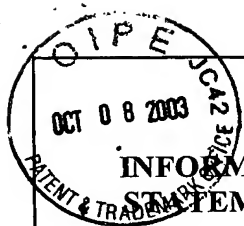
**FOREIGN PATENT DOCUMENTS**

| EXAMINER<br>INITIAL | DOCUMENT<br>NUMBER | DATE             | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|---------------------|--------------------|------------------|---------|-------|----------|-------------|----|
|                     |                    |                  |         |       |          |             |    |
|                     |                    |                  |         |       |          | YES         | NO |
|                     | WO 93/19770        | October 14, 1993 | PCT     |       |          | x           |    |
|                     | WO 01/00608        | January 4, 2001  | PCT     |       |          | x           |    |
|                     |                    |                  |         |       |          |             |    |

**OTHER DOCUMENTS**

| EXAMINER<br>INITIAL |  | AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.   |
|---------------------|--|--|
|                     |  | MacPeck, Donald L. et al., "Synthesis of Glycidic Esters by Epoxidation of $\alpha,\beta$ -Unsaturated Esters with Peracetic Acid," J. Am. Chem., 1959, Vol. 81, pp. 680-683 |
|                     |  | Emmons, William D. et al., "Peroxytrifluoroacetic Acid. IV. The Epoxidation of Olefins," J. Am. Chem., 1955, Vol. 77, pp. 89-92  |
|                     |  | Ho, Winston et al., "Alkylglycidic Acids: Potential New Hypoglycemic Agents," J. Med. Chem., 1986, Vol. 29, pp. 2184-2190  |
|                     |  | Lieberman, Herbert A. et al., <u>Pharmaceutical Dosage Forms: Tablets</u> , Volume 2, 2 <sup>nd</sup> Ed., Marcel Dekker, Inc., New York (1990), pp. 107-200                 |

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| EXAMINER  | DATE CONSIDERED |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |                 |



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|                     | 4,554,381        | November 19, 1985 | Desbois       |       |          |                |
|                     | 5,723,485        | March 3, 1998     | Gungor et al. |       |          |                |
|                     | 3,254,094        | May 31, 1966      | Ross          |       |          |                |

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|---------------------|--------------------|------|---------|-------|----------|-------------|----|
|                     |                    |      |         |       |          | YES         | NO |
|                     |                    |      |         |       |          |             |    |

**OTHER DOCUMENTS**

| EXAMINER<br>INITIAL |  | AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.  |
|---------------------|--|---|
|                     |  | Database CAPLUS on STN, Chemical Abstracts, CA: 129:244921, Freskos et al., "Preparation of aromatic sulfonyl alpha-hydroxy hydroxamic acid compounds as matrix metalloprotease inhibitors"   |
|                     |  | Database CAPLUS on STN, Chemical Abstracts, CA:128:75188, Takahashi et al., "Preparation and formulation of aryl sulfides, sulfoxides, and sulfones as matrix metalloproteinase inhibitors"   |
|                     |  | Database CAPLUS on STN, Chemical Abstracts, CA: 136:12767, Shusarek et al., "Color photographic thermally processable film comprising blocked developer compound"   |
|                     |  | Database CAPLUS on STN, Chemical Abstracts, CA: 86:171116, Buettner et al., "Trifluoromethyl-substituted aminobenzonitriles"  |
|                     |  | Database CAPLUS on STN, Chemical Abstracts, CA: 108:150026, Tucker et al., "Resolution of the non-steroidal antiandrogen 4'-cyano-3-(4-fluorophenylsulfonyl)-2-hydroxy-2-methyl-3'-(trifluoromethyl) propionanilide and the determination of the absolute configuration of the active enantiomer" |
|                     |  | Database CAPLUS on STN, Chemical Abstracts, CA: 2002:414656, James et al., "A two-step synthesis of the anti-cancer drug (r,S)-bicalutamide"  |
|                     |  | Database CAPLUS on STN, Chemical Abstracts, CA:120:191513, Horschler von Locquenghien et al., "Preparation of oxiranecarboxylates and analogs"  |
|                     |  | Database CAPLUS on STN, Chemical Abstracts, CA:89:90113, Rastetter, et al. "3,5-Dinitroperoxybenzoic acid. A crystalline, storable substitute for peroxytrifluoroacetic acid"   |
|                     |  | Database CAPLUS on STN, Chemical Abstracts, CA:134:326279, Ekwuribe, et al. "Asymmetric synthesis and antiandrogenic use of enantiomers of Casodex (bicalutamide) and derivatives from enantiomers of citramalic acid or proline"   |

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